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| 06/07/2001                          | Roderic O'Conor Cole | PC10717A  | 8847   |
| 90 01/26/2004                       |                      | EXAM  | INER   |
| 23913 7590 01/26/2004<br>PFIZER INC |                      | CELSA, BENNETT M  |  |
|                                     |                      | ART LINIT   | PAPER NUMBER   |
|                                     |                      | 1639  |  |
|                                     | 06/07/2001           | 06/07/2001 Roderic O'Conor Cole 90 01/26/2004  D STREET STOP 49 | 06/07/2001 Roderic O'Conor Cole PC10717A  90 01/26/2004 EXAM  CELSA, BE  D STREET  STOP 49 |

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.  | Applicant(s)  |     |
|---|--|---|-----|
|   | 09/876,784   | COLE ET AL.   |     |
| Office Action Summary   | Examiner   | Art Unit  |     |
|   | Bennett Celsa  | 1639  |     |
| Th MAILING DATE of this communicat  | ion appears on the cover she t   | with the correspondence address   |     |
| eriod for Reply   |  |   |     |
| A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNICA  - Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communica  - If the period for reply specified above is less than thirty (30) day  - If NO period for reply is specified above, the maximum statutor  - Failure to reply within the set or extended period for reply will, I  - Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b). | FION.  CFR 1.136(a). In no event, however, may stion.  ys, a reply within the statutory minimum of ty period will apply and will expire SIX (6) Means to be statute, cause the application to become | a reply be timely filed  hirty (30) days will be considered timely.  ONTHS from the mailing date of this communication.  ABANDONED (35 U.S.C. § 133). |     |
| 1) Responsive to communication(s) filed or  | n  |   |     |
| ,   | This action is non-final.  |   |     |
| , <u> </u>  | _  | ottore proceedation as to the marite is   |     |
| 3) Since this application is in condition for closed in accordance with the practice u  |  |   |     |
| sposition of Claims   |  |   |     |
| 4) Claim(s) 1-6 is/are pending in the application   | ation.   |   |     |
| 4a) Of the above claim(s) 6 is/are withdr   | awn from consideration.  |   |     |
| 5) Claim(s) is/are allowed.   |  |   |     |
| 6)⊠ Claim(s) <u>1-5</u> is/are rejected.  |  |   |     |
| 7) Claim(s) is/are objected to.   |  |   |     |
| 8) Claim(s) are subject to restriction  | and/or election requirement.   |   |     |
| pplication Papers   |  |   |     |
| 9) The specification is objected to by the Ex   | kaminer.   |   |     |
| 10) The drawing(s) filed on is/are: a)  | ☐ accepted or b)☐ objected t   | o by the Examiner.  |     |
| Applicant may not request that any objection  |  |   |     |
| Replacement drawing sheet(s) including the  | ·  |   | ).  |
| 11) The oath or declaration is objected to by   | the Examiner. Note the attach  | led Office Action or form PTO-152.  |     |
| iority under 35 U.S.C. §§ 119 and 120   |  |   |     |
| 12) Acknowledgment is made of a claim for   | foreign priority under 35 U.S.C  | C. § 119(a)-(d) or (f).   |     |
| a) ☐ All b) ☐ Some * c) ☐ None of:<br>1. ☐ Certified copies of the priority doc   | uments have been received.   |   |     |
| 2. Certified copies of the priority doc   | uments have been received in   |   |     |
| 3. Copies of the certified copies of the  |  | en received in this National Stage  |     |
| application from the International  * See the attached detailed Office action for   |  | ot received.  |     |
| 13) Acknowledgment is made of a claim for d   | omestic priority under 35 U.S.   | C. § 119(e) (to a provisional application   | on) |
| since a specific reference was included in 37 CFR 1.78.   | the first sentence of the specif   | ncation or in an Application Data She   | et. |
| a) ☐ The translation of the foreign langua  | age provisional application has  | been received.  |     |
| 14)☐ Acknowledgment is made of a claim for d  | omestic priority under 35 U.S.   | C. §§ 120 and/or 121 since a specific   |     |
| reference was included in the first sentence  | ce of the specification or in an a   | Application Data Sheet. 37 CFR 1.78.  | ٠.  |
| achment(s)  |  |   |     |
| Notice of References Cited (PTO-892)  |  | v Summary (PTO-413) Paper No(s)   |     |
| Notice of Draftsperson's Patent Drawing Review (PTO-<br>⊠ Information Disclosure Statement(s) (PTO-1449) Paper  |  | f Informal Patent Application (PTO-152)   |     |
| Information Disclosure Statement(s) (PTO-1449) Paper  | No(s) <u>11/6/03</u> . 6) Other:   | •   |     |
|   |  |   |     |

Art Unit: 1639

### DETAILED ACTION

## Status of the Claims

Claims 1-6 are currently pending.

Claims 1-5 are under consideration.

Claim 6 is withdrawn from consideration as being directed to a nonelected invention.

# Election/Restrictions

Applicant's election without traverse of Group I (claims 1-5) and mass spectrometer as a species in the correspondence dated 11/6/03 is acknowledged.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1639

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols US Pat. No. 6,012,488 (1/00: filed 9/98) and Maiefski et al. 6,309,541 (10/01: filed 10/99.

The presently claimed invention is directed to:

A method of analyzing multiple compound samples (e.g. libraries) using a device (e.g.

mass spectrometer) having a single input channel for compounds comprising:

i) introducing multiple compound samples into corresponding multiple separate solvent

flow streams having:

a means to connect each stream to the analysis device and

a means to timely introduce a stream to the analysis device

to form a single segmented flow stream having separate segments, with each segment

containing no more than one of said multiple compound samples

ii) introducing the segmented flow stream into the analysis device which is selectively

operated under conditions specific for each compound in the flow stream;

iii) correlating the input of said samples with the segmented flow stream to a timed

output analysis of said compounds whereby specific compounds are correlated to

specific analysis results; and

iv) wherein output analysis for compound samples with known analytical properties and

solvent function as demarcation lines between results of compounds being analyzed.

Nichols discloses a method for analyzing a sample comprising "a plurality of compounds" (e.g. a library) by separating the sample (e.g. purifying using HPLC) into a plurality of different sample flows (e.g. streams) each containing a different compound

Art Unit: 1639

and then flow a small slug of each sample at a time (e.g. "a means to timely introduce") to the detector (e.g. "analysis device" i.e. a mass spectrometer), with a slug of solvent between the slugs of different samples to identify the beginning and end of each sample slug. See e.g. Nichols Abstract; claims; col. 1 lines 1-27 and figures. The Nichols reference further discloses "a means to connect each stream to the analysis device" and "a means to timely introduce a stream to the analysis device to form a single segmented flow stream having separate segments, with each segment containing no more than one of said multiple compound samples" which is identical to that disclosed in the present specification. E.g. compare the reference figures (e.g. figures 1-3) to the present specification figures (e.g. figures 1-3). See also Nichols col. 1, lines 28-col. 2.

The Nichols reference method differs from the presently claimed method in the failure of the Nichols reference to specifically teach:

- ii) introducing the segmented flow stream into the analysis device which is selectively operated under conditions specific for each compound in the flow stream;
- iii) correlating the input of said samples with the segmented flow stream to a timed output analysis of said compounds whereby specific compounds are correlated to specific analysis results; and
- iii) wherein output analysis for samples of any compounds with known analytical properties and solvent function as demarcation lines between results of compounds being analyzed (e.g. the use of a control).

Art Unit: 1639

The Maiefski et al. reference teaches a multiple channel high throughput purification system for purifying a plurality of samples, preferably four or more samples from a chemical library, utilizing a mass spectrometer for analyzing the sample to determine if a target compound is within the sample portion. E.g. see Abstract. The Maiefski et al. reference further teaches that "sample management during the purification process" is a known problem in the art of conventional purification processes of large chemical libraries (See e.g. col. 2, especially lines 59-67). The Maeifski reference solves this problem by automation e.g. by tracking the samples (e.g. bar codes) utilizing a bar code reader and computer controlled spectrometer (e.g. see col. 7-8) which permits sample tracking, timed sample movement and mass spectrometer sample readings to permit spectrometer sample identification, analysis and timed correlation between sample and results wherein the sampled compounds are compared with known analytical and solvent function (e.g. the use of a control "as a demarcation ... between results of compounds being analyzed"). See e.g. Col. 7-8; col. 17-18; and patent claims (e.g. " ... detector being configured to detect at least one sample component within the respective sample flow ... ".

One of ordinary skill in the art would be motivated to automate the Nichol's reference device including the mass spectrometer to permit sample tracking, timed compound analysis and compound result correlation; and the use of a compound control for means of sample comparison as taught by the Maiefski reference since the Maeifski reference addresses library compound purification and analytical problems which are shared by the Nichols reference method. Accordingly, the Nichols method

Page 6

and apparatus faces the same problems addressing the purification and screening of library compounds as faced by Maeifski and thus one of ordinary skill in the art would be motivated to adopt the automation solution adopted by the Maefski reference.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Nichol's reference method and apparatus in the matter taught by the Maeifski reference in order to overcome the sample management problems of purification and analysis of library compounds and thus arrive at the presently claimed invention with a reasonable expectation of success.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 703-305-7556. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

B.C. January 22, 2004 Bennett Celsa Primary Examiner Art Unit 1639